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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,783	05/16/2000	NEIL P. DESAI	420042000126	2878

25226 7590 01/03/2007
MORRISON & FOERSTER LLP
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EXAMINER	
VU, JAKE MINH	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/446,783	DESAI ET AL.	
	Examiner	Art Unit	
	Jake M. Vu	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73 and 74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73 and 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 09/29/2006 and 08/10/2006; Request for Corrected Filing Receipt and Request for Continued Examination filed on 08/10/2006. Claims 73 and 74 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/10/2006 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 73 and 74 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 6,537,579; 5,362,478; 5,498421; 5,505,932; 5,508,021; 5,512,268; 5,635,207; 5,639,473; 5,650,156; 5,665,382; 5,665,383; 5,916,596; 5,560,933; and 5,439,686. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patents recite a composition comprising of: a water insoluble pharmacologically active agent, wherein said agent is a solid or liquid substantially completely contained within a polymeric shell, wherein the largest cross-sectional dimension of said shell is no greater that about 10 microns, wherein said polymeric shell comprises a biocompatible polymer which is substantially crosslinked by way of disulfide bonds, and wherein said polymeric shell containing pharmacologically active agent therein is suspended in a biocompatible aqueous liquid (see US 5,439,686, claim 1). Wherein said pharmaceutically active agent is taxol (see claim 2). Wherein said polymer, prior to crosslinking, has covalently attached thereto disulfide linkages (see claim 11). Wherein biocompatible polymer is the crosslinked protein albumin (see claim 15). The only difference between the instant claims and the patents recited claims is the active ingredient, which is taxane. It would have been obvious to one of ordinary skill in the art to select taxane, because taxane is the genus that contains only two species: taxol and docetaxel.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 73 is rejected under 35 U.S.C. 102(e) as being anticipated by VIOLANTE et al (US 5,741,522) in light of MARKUS et al. *The disulfide bonds of human serum albumin and bovine gamma-globulin.* J Am Chem Soc. 1957 Jan 05; 79(1): 134-39.

Applicant's claims are directed to a composition comprising of: a solid core of water insoluble drug nanoparticles coated with albumin, wherein the albumin is crosslinked by disulfide bonds.

VIOLANTE disclosed a composition comprised of: a solid core of water insoluble drug ultra-small particles (see abstract), such as (iodipamide ethyl ester) IDE particles, coated with albumin (see col. 13, Example III). Note, the IDE particles are within the scope of "drug" nanoparticles as IDE is a CT contrast agent (see col. 7, line 43+). Thus, the particles are clearly within the scope of nanoparticles as claimed by Applicant. Additional disclosures include: various therapeutic agents (e.g. anti-neoplastics, 5fdU, etc) may be used in the particles (see col. 7, line 55+ and col. 9 and col. 11, line 45+).

VIOLANTE does not disclose that the albumin is crosslinked by disulfide bonds; however, this limitation is inherent to all albumins as disclosed by MARKUS.

MARKUS teaches that albumin has disulfide bonds that are cross-linked (see abstract). Thus, the limitation of "where in the albumin is crosslinked by disulfide bonds" has no patentable weight.

Claims 73 and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by LIVERSIDGE et al (US 5,399,363) in light of MARKUS et al (cited supra).

Applicant's claims are directed to a composition comprising of: a solid core of water insoluble drug nanoparticles, such as taxane, coated with albumin, wherein the albumin is crosslinked by disulfide bonds.

LIVERSIDGE disclosed a composition comprised of: a solid core of water insoluble drug nanoparticles (see title and abstract), such as taxol (see col. 3, line 20), which is a taxane, coated with albumin (see col. 4, line 48 and col. 9, Examples 2-4).

LIVERSIDGE does not disclose that the albumin is crosslinked by disulfide bonds; however, this limitation is inherent to all albumins as disclosed by MARKUS.

MARKUS teaches that albumin has disulfide bonds that are cross-linked (see abstract). Thus, the limitation of "where in the albumin is crosslinked by disulfide bonds" has no patentable weight.

Applicant's arguments filed 08/10/2006 have been fully considered but they are not persuasive.

Applicant's main relevant argument to the current rejection is that VIOLANTE "fails to disclose or suggest an article of manufacture comprising a dry powder or liquid formulation of water insoluble drug and at least one protein, wherein the formulation comprises a solid core of water insoluble drug nanoparticles coated with the protein, and wherein the protein is albumin and the albumin is crosslinked by disulfide bonds." Since Applicant failed to point which limitation is missing, the Examiner is assuming the missing limitation is the newly amended limitation of "wherein the albumin is crosslinked by disulfide bonds". The Examiner finds this argument unpersuasive, because this limitation is inherent to albumin as discussed above.

Telephonic Inquiries

The Request for a telephone interview is acknowledged. Applicant is invited to telephone the Examiner at the number provided below to schedule the interview.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jake M. Vu, PharmD, JD
Art Unit 1618.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER